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09/291,656	03/03/1999	MARC PETERS-GOLDEN	UM-03662	2349

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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/291,656
Filing Date: March 03, 1999
Appellant(s): PETERS-GOLDEN ET AL.

Peter G. Carroll
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 28, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

This appeal involves claims 22-25 and 27-37.

Claims 1-21 and 26 have been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is mostly correct. No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 22-25 and 27-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gosselin et al. (USP 5,789,441; priority to February 15, 1996).

Gosselin et al. teach leukotriene LTB_4 in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example). The term "LTB_4" includes leukotrienes C_4, D_4, and E_4 (col. 6, line 52).

Gossellin et al. do not expressly teach that to include an antibiotic to the a solution comprising a sterile liquid and a leukotriene. However, at col. 5, lines 24-29, Gossellin et al. states that the invention provides for the use of an LTB_4 agent as a therapeutic against Gram + and –

infections, or fungal infections alone or in association with other antibacterial or antifungal agents.

Therefore, it would have been obvious to a person having ordinary skill in the art to include an antibiotic in a solution comprising a sterile liquid and a leukotriene (Claims 22, 26, 27, 28, 32, 33, 37), wherein the leukotriene is LTB_4 (Claims 23, 29, 34), or wherein the leukotriene is a cysteinyl leukotriene (Claim 24, 3, 35) such as leukotrienes C_4, D_4, and E_4 (Claims 25, 31, 36) because Gosselin et al. suggests to use LTB_4 with an antibacterial or antifungal agent against Gram+ and – infections, or fungal infections.

While the claims recite that the solution aerosolized or is in an endotracheal tube, a bronchoscope, or a nebulizer, for example, these phrases are given no patentable weight. See *Union Oil Co. of California* v. *Atlantic Richfield Co.*, 54 USPQ2d 1227, *In re Rosicky*, 125 USPQ 341; *In re Riden et al.*, 138 USPQ 112; *In re Lerner* 169 USPQ 51. Therefore, the Claims are obvious over Gosselin et al. as set forth above.

(10) Response to Argument

Claims 22-25 and 27-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gosselin et al. (USP 5,789,441; priority to February 15, 1996).

Argument A:

Appellants urge that Gosselin et al. is not prior art against their invention because Gosselin et al. is a CIP of parent application 08/602,059 and should not get priority to the parent filing date of February 15, 1996. Appellants argue that the parent application does not teach sterile solutions of leukotrienes or to add antibiotics to the sterile solutions of leukotrienes. The Examiner found support for sterile solutions of leukotrienes and to add antibiotics to the sterile solutions of leukotrienes in '059 before the rejection was ever made, and Appellants have submitted a copy of the specification of this abandoned file into this instant record on January 20, 2004. In 08/602,059, support for sterile solutions of leukotrienes can be found in the Examples

at pages 13-15. As noted in the rejection, Example I provides sterile solutions of leukotrienes. A specific showing that Gosselin et al. were indeed in possession of sterile solutions in their parent application can be found, for example in Example 5 at page 15 wherein the specification states:

Comparative antiviral effects of LTB4 and acyrlovir onEBV infection

PBMC (10^6 cells/ml) were cultured in micro-plates (96 wells) at 2 x 10^5 cells/well and infected with EBV (10^7 TFU/ml) as described in Example I. At one hour post-infection, cell cultures were treated with LTB4 (3 nM) or with different concentrations of Acyclovir (acycloguanosine), ie. 1000 or 3000 nM. After seven days of incubation, clump formation (Fig. 5A) and EBNA synthesis (Fig. 5B) were evaluated as described in Example I.

Therefore, Gosselin et al. were in possession of sterile solutions of leukotrienes because they used these solutions in cell culture AND kept the cell culture alive for at least seven days, indicating that the experiment was not "quick and dirty" but intended to be performed under aseptic techniques. **Note also that this Example 5 in the Gosselin et al. parent is mostly the same as presented in the Gosselin et al. patent.**

Regarding the inclusion of antibiotic agents into the sterile solution of leukotrienes, the parent '059 application states at page 8, para. 4:

In accordance with the present invention, there is provide the use of LTB4 agent as a therapeutic aqent against bacterial Gram + and - infections or fungal infections, alone or in association with other antibacterial or antifungal agents.

Therefore, Gosselin et al. provide strong suggestion and motivation in their parent application for the inclusion of antibacterial or antifungal agents in their sterile, therapeutic solutions of leukotrienes. **Note that this is the same passaged used in the Gosselin et al. patent at Col. 5, lines 24-29, as cited in the rejection.**

Taken in total, Appellants concerns that the parent application 08/062,059 does not provide support for the sterile solutions of leukotrienes or for the addition of antibacterial agents into the sterile solutions of leukotrienes is unfounded. The priority date afforded Gosselin et al. is correctly set to February 15, 1996.

Argument B:

Appellants urge that neither the Gosselin et al. patent or parent offer support for aerosol solutions of leukotrienes with antibiotic agents. In response, The Gosselin et al. patent discusses aerosols at Col. 11, line 32. Further, each droplet within an aerosol is the sterile solution of leukotriene taught in the Gosselin et al. patent and parent. Therefore, whether one has a beaker of the solution of sterile leukotriene or a droplet of the solution of sterile leukotriene, the solution is not discernible. Thus, an aerosol form of the solution of Gosselin et al. does not differentiate over the solution of leukotriene taught in Gosselin et al. Thus, while Appellants find the citation of *Union Oil* misplaced because it is drawn to the concept that a composition is suitable for an intended use, the instant claims phrase "wherein said solution is an aerosol" is also a form of the solution in a particular form for an intended use. Also, "aerosol" describes a dosage from, not the solution itself. See also Gosselin et al. at Col. 11, lines 31-32, wherein an aerosol is a dosage form of the sterile solution of leukotriene.

Appellants argue that *Rosicky* (and *Lerner*) did not provide the advantages of pharmaceutical compositions while Appellants offer the advantages of aerosols comprising sterile solutions of leukotrienes. Gosselin et al. demonstrate that leukotrienes are antiviral, antibacterial, and antifungal agents. Thus, the advantages of pharmaceutical compositions of leukotrienes are taught in Gosselin et al.

Appellants provide evidence that *Riden* is no longer a valid holding.

Argument C:

Appellants urge that the Examiner admits that Gosselin et al. do not teach leukotriene/antibiotic combinations. The Examiner agrees that Gosselin et al. do not expressly, physically make this solution; otherwise, the claimed invention would be anticipated by Gosselin et al. Rather, Gosselin et al. does suggest that because they found that the leukotrienes are antiviral, antibacterial, and antifungal, then leukotrienes could be combined with antibacterial or antifungal agents to treat Gram + and – bacterial infections and fungal infections. Thus, Gosselin et al. provide the suggestion and motivation to combine leukotrienes with antibiotic agents. It would be predictable that these solutions would be able to treat Gram + and – infections and fungal infections because Gosselin et al. demonstrate that the leukotrienes are antibiotic themselves, and other antibiotic agents are well-known in the art.

The rejection under 35 USC 103 above are consistent with case law. Appellants are referred to *In re Kerkoven* (205 USPQ 1069) in which it was shown to be *prima facia* obvious to combine two compositions, each of which is taught by the prior art to be used for that very same purpose. *Ex Parte Quadranti* (25 USPQ2d 1071) also sets forth this precedent, in that the use of materials in combination, each of which is known to function for the intended purpose, is generally held to be *prima facia* obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

April 8, 2006

Conferees
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